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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,149	02/19/2004	Ghassan S. Kassab	KASSAB.003A	5030

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
ROGERS, KRISTIN D	
ART UNIT	**PAPER NUMBER**
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/31/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/782,149	KASSAB ET AL.	
	Examiner	Art Unit	
	Kristin D. Rogers	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *1-21 and 42-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-41* is/are rejected.

7)☒ Claim(s) *27 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-21 and 42-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 23, 2006.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gat et al. (WO 98/35611) in view of Jansen et al. (7069072). In regard to claims 22 and 29-30, Gat et al. shows a method for measuring the cross-sectional area of a targeted treatment site comprising introducing an impedance catheter (14) into the treatment site; providing constant electrical current flow to the site (12); injecting a fluid into the treatment site to measure conductivity (page 11, lines 2-5; page 13, lines 2-14); and calculating the cross-sectional area of a treatment site (page 11, lines 2-5). Gat et al. is silent regarding the fluid injected into the treatment site and measuring a first and second conductance value. Jansen et al. teaches a catheter for measuring the cross-sectional area of a body lumen comprising injecting a first and second fluid, saline solution into the treatment site and a first and second conductance value is measured (column 2,line 30 to column 6, line 16) for measuring the cross-sectional area of the body lumen. Therefore it would have been obvious to one of ordinary skill in the art at

the time of the invention to modify Gat et al. with a liquid such a saline and measurement of a first and second conductance value as taught by Jansen et al. since such modification would provide a fluid having a different conductance of blood for indicating the treatment site and measuring the cross-sectional area of the site.

7. In regard to claims 23-26, Gat et al. shows that the impedance catheter can be used in a body lumen including the blood vessel (page 10, lines 17-18). The Examiner note that claims 23-26, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

8. In regard to claims 31 and 32, Gat et al. shows a method of selecting a catheter to be introduced into the treatment site based on the measurement of a first conductance and a first current density at the treatment site and calculating a first nodal voltage and a first electrical field (page 7, line 20 to page 8, line 4).

9. In regard to claim 40, the impedance catheter (14) includes a pressure transducer 20 and 22 (page 7, lines 20-26, page 8, lines 1-2).

10. In regard to claim 41, Gat et al. shows the steps of measuring a first pressure from the pressure transducer near the treatment site and calculating the cross-sectional area of the treatment site based on the pressure (page 4, lines 1023 and page 7, lines 20-26).

11. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gat et al. and Jansen et al. as applied to claim 32 above, and further in view of

Boneau. Gat et al. and Jansen et al. show the invention as claimed by the Applicant recited above, including calculating a nodal voltage and the use of on-line measurement processing system (software and analysis) (CPU Figure 2) for determining the appropriate of treatment, but is silent regarding determining the appropriate catheter size. Boneau teaches an endovascular support device for treatment of vascular narrowing comprising a balloon catheter 100 including a stent 10 capable of being distended to the desired lumen size and implanted into the treatment site. The size of the stent is based on the cross-sectional area of the treatment site (paragraphs 13,14,16,20,39 and 42). Therefore it would have been obvious to modify Gat et al. and Jansen et al. with an inflatable balloon catheter capable being various sizes as taught by Boneau since such modification would provide means for treating a stenotic lesion with a catheter that is variable in size based on the cross-sectional area of the treatment site.

12. Claims 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gat et al. and Jansen et al. as applied to claim 22 above, and further in view of Greco et al. (6666828) and Boneau (20020049488). Gat et al. and Jansen et al. show the invention as claimed by the Applicant recited above, including a sleeve for contacting the interior wall of the artery and breaking up the stenotic lesion. Gat et al. is silent regarding if the sleeve member is an inflatable balloon comprising a stent. Greco et al. teaches a disposable balloon catheter (20) capable of measuring impedance (electrodes 80A-80D), measuring the cross-sectional area of the body lumen (column 1, lines 57-60). Greco et al. further teaches that the balloon catheter may comprise means

for drug delivery (column 7, lines 10-17). Greco et al. is silent regarding the drug delivery means. Boneau teaches an endovascular support device for treatment of vascular narrowing comprising a balloon catheter 100 including a stent 10 capable of being distended to the desired lumen size and implanted into the treatment site. The balloon is inflated and the stent is released and implanted into the treatment site. Furthermore, the size of the stent is based on the cross-sectional area of the treatment site (paragraphs 13,14,16,20,39 and 42). Therefore it would have been obvious to modify Gat et al. and Jansen et al. with an inflatable balloon capable of providing drug delivery means as taught by Greco et al. and a balloon catheter having drug delivery means comprising a stent as taught by Boneau since such modification would provide means for treating a stenotic lesion with a stent based on the cross-sectional area of the treatment site.

Allowable Subject Matter

Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is

571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDR

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